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IN THE

Supreme Court of the United States

OCTOBER TERM, 1961.

No. 929

ELLIS RESEARCH LABORATORIES, INC., AND ROBERT W. ELLIS, AN INDIVIDUAL,
Petitioners,

vs.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT.

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT.

To the Honorable, the Chief Justice of the United States and the Associate Justices of the Supreme Court of the United States:

Petitioners, Ellis Research Laboratories, Inc., and Robert W. Ellis, respectfully pray that a writ of certiorari issue to the United States Court of Appeals for the Seventh Circuit to review a final judgment of that Court affirming a judgment and decree of permanent injunction of the United States District Court, Northern District of Illinois, Eastern Division.

OPINIONS BELOW

The opinion of the Court of Appeals for the Seventh Circuit is not yet reported but a copy thereof is attached to this petition as Appendix A hereto, *infra* pages 29 to 37. The date and time of its entry was March 22, 1962.

The Findings of Fact, Conclusions of Law and Injunction Decree of the District Court are found at pp. 332 to 342 of the Appendix in the Court of Appeals for the Seventh Circuit and filed herewith. The date of their entry was June 14, 1961.

JURISDICTION

The jurisdiction of this Court is invoked pursuant to Section 371(f) (4) of 21 U. S. C. (also cited as 21 U. S. C. A. Section 371(f) (4)) of the Federal Food, Drug and Cosmetic Act, June 25, 1938, 675, Section 1, 52 Stat. 1040.

QUESTIONS PRESENTED

Three important federal questions presented herein are:

1. Is a harmless diagnostic instrument, in the case at bar a galvanometer called a MICRO-DYNAMETER, shipped to licensed practitioners for their use only as an aid in the diagnosis of their patients, exempt from labeling bearing adequate directions for use under the mandatory language of the exemption provision of 21 U. S. C. (21 U. S. C. A.) 352(f), and under the express language of regulations thereunder 21 C. F. R. Revised 1955, Section 1.106(d) and Section 1.106(e) or like regulations required under the mandatory language of said statute?

2. Is an accused in an action brought for an injunction under Section 302(a) of the Federal Food, Drug and Cosmetic Act (21 U. S. C. 332(a)) to enjoin and restrain violations of Section 301 of the Act (21 U. S. C. 331) for misbranding within the meaning of Section 502(a) of the

Act (21 U. S. C. Section 352(a) and (f) (1)), entitled to a jury trial of the issues of fact before an injunction may issue in obedience to the Seventh Amendment to the Constitution of the United States, Federal Rules of Civil Procedure Rule 38(a) and (b) and 39(a), and the Federal Food, Drug and Cosmetic Act itself, 21 U. S. C. Section 334(b) and 332(b)?

3. Is a Decree of Injunction which restrains the alleged past violations of this Federal Act, but also restrains operations and business transactions in the future, unless the shipment of a commodity in interstate commerce is accompanied by written, printed or graphic matter described abstractly only, and calling for some future affirmative act of the restrained Defendants, fatally defective for indefiniteness and generality under the decisions of the United States Supreme Court and of certain Courts of Appeals of the United States, and under Rule 65(d) of the Federal Rules of Civil Procedure?

THE STATUTES AND THE RULES INVOLVED.

1. The statutes and rules involved in the determination of the first question are: The Federal Food, Drug and Cosmetic Act as a whole, June 25, 1938 c. 675, Section 1, 52 Stat. 1040, especially Section 352(a) and (f) (1) thereof, and any regulations thereunder adopted or which must be adopted by the Secretary, which, in the case at bar were 21 C. F. R. 1.106(d) and 1.106(e) and 1.106(m), to be found in 21 C. F. R. Revised 1955 and Pocket Parts 1960, Section 1.106(d), 1.106(e) and 1.106(m).

2. The statutes and rules involved in the determination of the second question are: The Federal Food, Drug and Cosmetic Act as a whole, June 25, 1938 c. 675, Section 1, 52 Stat. 1040, and especially 21 U. S. C. (21 U. S. C. A.) Section 331, 332(a) and (b) and Section 334(a) and (b);

also the Seventh Amendment to the Constitution of the United States and Rules 38(a) and (b) and Rule 39(a) of the Federal Rules of Civil Procedure, and the rules upon jury trial and the obligation of the Federal Courts to accord the same to a litigant demanding same as a matter of right upon legal and controverted issues of fact to be determined by a jury before an injunction may issue, which rules are declared in the decisions of the Courts of Appeals for the Eighth and Ninth Circuits in conflict with the decision below of the United States Court of Appeals for the Seventh Circuit:

Leimer v. *Woods*, 196 F. 2d 828 (CA 8).

Bruckman v. *Hollzer*, 152 F. 2d 730 (CA 9).

3. The statutes and rules involved in the determination of the third question are as follows: The Federal Food, Drug and Cosmetic Act as a whole, June 25, 1938 c. 675, Section 1, 52 Stat. 1040, including and particularly Section 332(a) and (b) of 21 U. S. C., and Rule 65(d) of the Federal Rules of Civil Procedure; and the rules upon the defective nature of an indefinite injunction under Rule 65(d), and embodied in the decisions of the United States Supreme Court and the Courts of Appeals as follows:

Schine Chain Theaters v. *U. S.*, N. Y. 1948, 68 Sup. Ct. 947, 334 U. S. 110, Pet. Denied 68 Sup. Ct. 1343, 334 U. S. 831.

Hartford-Empire Co. v. *U. S.*, 65 Sup. Ct. 373, 323 U. S. 386, and supplemented on other grounds 65 Sup. Ct. 815, 324 U. S. 570, Mandate conformed to 65 F. Supp. 271.

Corica v. *Ragan*, 140 F. 2d 496 (CA 7).

Schwegmann Bros. Giant Super Market v. *Hoffman-LaRoche, Inc.* (CA 5), 221 Fed. 2d 326, Cert. Denied 76 Sup. Ct. 77, 350 U. S. 830.

Russell House Transfer & Stg. Co. v. U. S. (CA 5), 189 F. 2d 349.

N. L. R. B. v. Kuiper Motors (CA 9), 152 F. 2d 816, Modified on other grounds 154 F. 2d 1007.

Joseph Bancroft & Sons Co. v. Shelley Knitting Mills (CA 3), 268 F. 2d 569.

STATEMENT OF THE CASE.

The first question sought to be determined herein is whether or not a harmless diagnostic device, shipped to physicians only, for their use only, is exempt under the proviso clause of 21 U. S. C. Section 352(f) (1) from the labeling requirements of adequate directions for use. This statute is also entitled 21 U. S. C. A. Section 352(f) (1) and reads as follows:

"Section 352. Misbranded drugs and devices.

"A drug or device shall be deemed to be misbranded—

"(f) unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *provided*, that where any requirement of clause (1) of this subsection, as applied to any drug or a device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement."

The diagnostic instrument involved herein, which is called the MICRO-DYNAMETER, is a galvanometer (App. 71, Q. 14). (References to "App." refer to Appendix filed in the

Court of Appeals for the Seventh Circuit, below, and also now filed here). It provides a sensitivity permitting the measurement of electric current in the small fractions of amperes. When the human body is contacted by electrodes composed of dissimilar metals a voltaic cell is formed, and a scale reading is produced. The electric current flowing between electrodes of dissimilar metals, acting as a voltaic cell, when such electrodes are in contact with the human body, may be measured (App. 34, Answers to Interrogatories Nos. 1 and 3). The device has been shipped in interstate commerce since 1933, and after the applications for patents were granted it has been shipped in interstate commerce through the life of the patents which expired in 1958, the protection of the company resting now upon the trade name, the MICRO-DYNAMETER (App. 27, Par. 7).

The Defendants, Petitioners herein, require that a purchaser of a MICRO-DYNAMETER diagnostic instrument possess the minimum professional qualifications and education required by the law of the state in which he is licensed to practice to be a practitioner of the healing arts. The device is sold to any practitioner of the healing arts who is licensed to practice, and the Petitioners, Defendants below, determine whether a prospective purchaser of the MICRO-DYNAMETER possesses these qualifications by asking for his State License Number on the order form (App. 35, Answers to Interrogatories 10, 11 and 12).

The device is harmless, no matter how the instrument is used on the patient (App. page 272, Par. 436).

The regulations of the Food and Drug Administration in force and effect when the Complaint for Injunction was filed to be found in 21 C. F. R. Revised 1955 Section 1.106 (e) provided:

> "Title 21, C. F. R. Section 1.106 (e) *Exemptions for Drugs and Devices shipped directly to licensed practitioners, hospitals, clinics, or public health agencies for*

professional use. Except as provided in Paragraph (g) of this Section, a drug or device shipped directly to or in the possession of a practitioner licensed by law to administer the drug or to use or direct the use of the device, or ship directly to or in the possession of a hospital, clinic, or public health agency, for use in the course of the professional practice of such a licensed practitioner, shall be exempt from Section 502(f) (1) of the Act if it meets the conditions of Paragraphs (b) (2) and (3), (c) (2) and (3), or (d) (2) and (3) of this Section."

The District Court in which the Complaint was brought, the United States District Court for the Northern District of Illinois, Eastern Division, found as a conclusion of law:

> "8. The fact that the Micro-Dynameter device may or may not be sold and distributed only to licensed medical practitioners is not relevant in the present action" (App. p. 340, Par. 66).

The action below against Petitioners, who were doing business within the jurisdiction of the United States District Court for the Northern District of Illinois, Eastern Division, arose on a Complaint filed by Respondent under provisions of the Federal Food, Drug and Cosmetic Act, June 25, 1938, c. 675, Sec. 1, 52 Stat. 1040. The Petitioners were engaged in selling the device in interstate commerce and said device was generically classifiable as one within the meaning of the Act. The Complaint alleged violations of the Act in the literature accompanying the device to the physician customers of Petitioners, claiming misbranding under Sections 352(a) and (f) of 21 U. S. C.

The Complaint (App. pp. 3 to 14) filed by the Respondent, the United States of America, Plaintiff below, in the United States District Court for the Northern District of Illinois, Eastern Division, charged the Petitioners, Defendants below, with distributing the device known as the MICRO-DYNAMETER in interstate commerce with certain labeling in the

form of bulletins, books and printed matter accompanying the device (sent to licensed practitioners), representing that the device was adequate and effective for diagnosing any diseased condition and health status of man, which representations and suggestions were allegedly false and misleading in that the said device was not adequate or effective for diagnosing the same and that the device was misbranded in violation of the Act thereby. Therefore the said United States District Court had jurisdiction. The Complaint alleged in Paragraph 10 thereof (App. p. 10, par. 14) that the device has no diagnostic capability with respect to such conditions. The allegations of the Complaint were controverted in the Answer (App. pp. 14-21), in which the Defendants below, Petitioners herein, also alleged that the Plaintiff has an adequate remedy at law (App. p. 21). The Petitioners, Defendants below, made a timely demand for jury trial twice repeated, and a Motion to order Jury Trial (App. pp. 22, 23 and 24), demanding a jury trial as a matter of right.

The Respondent, Plaintiff below, moved to strike the demand for jury trial (App. p. 29, Par. 36), and the trial Court and the United States District Court granted said Motion of said Plaintiff to strike the said Defendants' jury demand (App. p. 29, Par. 38).

The said Order of the District Court granting the Motion to Strike said Demand for Jury Trial did not find that a right of trial by jury of some or all of the issues does not exist under the Constitution or statutes of the United States.

Rule 39(a) of the Federal Rules of Civil Procedure provides:

> "When trial by jury has been demanded as provided in Rule 38, the action shall be designated upon the docket as a jury action. The trial of all issues so demanded shall be by jury, unless * * * (2) the Court

upon Motion or of its own initiative finds that a right of trial by jury of some or all of those issues does not exist under the Constitution or statutes of the United States."

In affirming the action of the trial court in denying the Petitioners a jury trial, the Court of Appeals for the Seventh Circuit stated:

"Plaintiff sought only injunctive relief, and historically such an action has always been equitable in nature with the factual issues raised triable by the Court."

Section 334 of the Act, 21 U. S. C. A. Section 334(a) and (b) provide for enforcement for the misbranding of any device when introduced into or while in interstate commerce by said device being proceeded against on libel of information, and subsection (b) of the said Section 334 states:

"The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this Section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury."

This provided an adequate remedy at law, and specifically provided the intent of the Act to give a jury trial.

Such attempt was made some years prior against the MICRO-DYNAMETER device. The very device that was Government's Exhibit No. 1 in the trial in the District Court below was seized, and a Libel of Information filed against it on March 19, 1955 (App. p. 79, Par. 50 and 51). By virtue of the Section above quoted, Section 334(b) the Defendants were entitled to a jury trial in that case. It was concluded by a Consent Decree without prejudice, the device having been seized in the hands of an unlicensed practitioner on that occasion. Since then no claim was made

that the device was shipped thereafter to any but licensed practitioners (See Defendants' (Petitioners) Exhibit H, which is the original Court file in the said 1955 case, App. p. 182, Par. 261 and p. 183, App. 79, Par. 51; App. p. 27, Par. 34 and Answers to Written Interrogatories App. p. 35, Answers to 10-16—correlated with Interrogatories 9-16, App. pp. 31 and 32; also Answers to Interrogatories Nos. 5 and 8, App. p. 30, Par. 40 and p. 31, Par. 41, and App. pp. 38-50, inclusive). The Interrogatories and Answers were received in evidence (App. p. 81, Par. 56).

Thus the same device that was seized in the admiralty proceeding was the same one claimed to have been misbranded and by the same literature, and for shipment to licensed practitioners in both the 1955 admiralty case and in the Complaint for Injunction, with the same allegations of controverted fact.

The question of the right of the Petitioners, Defendants below, to a jury trial of said issues of fact upon this Complaint for Injunction is of great public importance because it involves whether by the mere device of asking for an injunction rather than for condemnation the accused may be deprived of a jury trial when the Act itself contemplates a jury trial in the seizure method, and even contemplates a jury trial for violation of an injunction in another provision of the Act, 21 U. S. C. A. Section 332 (b).

The Decree of the United States District Court for the Northern District of Illinois, Eastern Division, was a decree of injunction permanently restraining the Petitioners, Defendants below, from distributing to the licensed practitioners to whom they sell the galvanometer called the MICRO-DYNAMETER, all of the literature previously sent to them accompanying the device, which stated every disease, condition, symptom and purpose for which the article was intended to be used; then, at the same time the said

Decree further restrained the Petitioners from delivering the device in interstate commerce at all, "unless such device bears or is accompanied by written, printed or graphic matter which clearly states every disease, condition, symptom and purpose for which the article is intended to be used and for which it is represented by any means to the public;" and at the same time, the Court provided that, "jurisdiction of this Court is retained for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may hereinafter appear necessary and appropriate." (App. pp. 332-342 inclusive; the quoted provisions appearing at pp. 341, Par. 68 and 342.)

Comparing the decision of the Supreme Court of the United States in *Hartford-Empire Co.* v. *U. S.*, 323 U. S. 386, the aforesaid Decree in the case at bar is confiscatory, and goes beyond the jurisdiction and authority of the District Court of the United States rendering said Decree, and also goes beyond the authority and scope of the Federal Drug and Cosmetic Act itself, which is limited to the punishment for or restraint upon violations of the Act having to do with the misbranding of drugs or devices, without authority to punish in advance or restrain anticipated violations in the future. Contrary to Rule 65(d) of the Federal Rules of Civil Procedure, the said Order granting the said injunction was confiscatory, and fatally defective, in not describing in reasonable detail without reference to the Complaint or other document the act or acts sought to be restrained.

REASONS FOR THE GRANTING OF THE WRIT.

I.

One primary reason relied upon for the allowance of this Petition for a Writ of Certiorari is that the decision of the Court of Appeals for the Seventh Circuit, in the action below, affirming the judgment and decree of injunction of the District Court for alleged violation of Section 352(a) and (f) of the Federal Food, Drug and Cosmetic Act, is in direct conflict with the statutory exemption of the device in question from any labeling requirement bearing adequate directions for use, and this is an important public federal question of first impression requiring the construction of the meaning and interpretation of said express exempting provisions of the said Section 352(f), and of existing or mandatory regulations thereunder.

II.

A second primary reason relied upon for the allowance of this Petition for a Writ of Certiorari is that the decision of the Court of Appeals for the Seventh Circuit, in the action below, affirmed the decree of injunction of the District Court upon findings made by the Court upon controverted issues of fact without a jury, when trial by jury was timely demanded as a matter of right by Petitioners herein, and this Petition on this subject presents an important public federal question when the decision of the Court of Appeals for the Seventh Circuit is in direct and clear conflict with the intention of the Federal Food, Drug and Cosmetic Act itself that the accused shall be entitled to a jury trial for violations claimed thereunder, and in conflict with Rule 38(a) and (b) and 39(a) of the Federal Rules of Civil Procedure, and in conflict with the Seventh

Amendment to the Constitution of the United States, and in conflict with the decisions of Courts of Appeal for the Eighth and Ninth Circuits?

III.

A third primary reason relied upon for the allowance of this Petition for a Writ of Certiorari is that the decision of the Court of Appeals for the Seventh Circuit, in the action below, upheld the entry of a permanent injunction against the Petitioners incorporating in said decree a restriction against any shipments in interstate commerce unless the Petitioners obey by a future affirmative act, impossible of observance, an abstract, indefinite and general requirement, and this Petition for Writ of Certiorari presents an important public federal question because the affirmed decree of injunction is confiscatory; and the decision of the Court of Appeals for the Seventh Circuit upholding the same is in clear and direct conflict with Rule 65(d) of the Federal Rules of Civil Procedure, the fair intendment of the Federal Food, Drug and Cosmetic Act itself, which is limited to the invoking of remedies for past violations, and conflicts with important established precedents of the United States Supreme Court invalidating indefinite injunctive orders, and in conflict with a prior decision of the Court of Appeals for the Seventh Circuit itself, and with prior decisions of the United States Courts of Appeals for the Third Circuit, Fifth Circuit, and the Ninth Circuit.

ARGUMENT.

I.

At the threshold of the case we find an instrument which operates upon a principle universally accepted insofar as electrical phenomena within the human body are concerned (App. 123). We also find that the instrument in question has been in use since 1933. Upon the challenge against its utility we find that it was patented, and if the Court will refer to the claims in the Patents in Exhibits A, B, C, D, E, F and G, it will find that the literature complained of is in conformity therewith.

No Government witness contended that the Manual of Directions for the mechanical use of the device was not adequate or could not be readily followed. Nor is any complaint or contention made in that respect in this case.

The complaint made is that the literature accompanying the device expressing to the physician-purchasers thereof how they may find it useful to them in diagnosis is misleading. But the quoted provision of the U. S. Code found in 21 U. S. C. 352(f) introduces the subject of exemption of the drug or device from such requirement of "adequate directions for use" where any requirement of Clause (1) of the subsection (f) as applied to any drug or device, is not necessary for the protection of the public health. It is undisputed in this case that the device is absolutely harmless, and it is likewise undisputed that its user is not by the lay public but by physicians who are schooled in diagnosis.

Such licensed practitioners in the healing arts who are specially schooled in diagnosis are the purchasers of this device and apply the instrument in their practice. Their own judgment in the diagnosis of disease is what affects

the patient or the public, and not any information, or misinformation of the manufacturer of the device. The policy and purpose of the Act is to protect the public against harmful drugs, harmful foods, and deleterious devices. It is no function of the Secretary administering the Federal Food and Drug Act to police the healing arts. It is not the function of the Secretary to protect chiropractors and medical physicians against fraud and misrepresentation in general, or to enter into an academic judicial inquiry into dialectics. This is not the policy of the Act, which is addressed to the practical problem of consumer protection, and by "the consumer" is meant the innocent and uninformed public, not the specially informed and trained professional.

Accordingly, the Act itself imposes upon the Secretary the mandate to promulgate regulations exempting from any adequate directions for use any device, the use of which is not necessary for the protection of the public health, and this mandate has been specifically carried out by the Secretary with particular reference to devices shipped directly to licensed practitioners, hospitals, clinics, or public health agencies for professional use, or students to be trained as practitioners in the healing arts. Under said mandate of the statute and under the regulations adopted pursuant thereto, it is respectfully submitted that the Micro-Dynameter is exempt from any labeling requirement whatever, and that the Court erred in finding that the fact that the Micro-Dynameter device may or may not be sold and distributed only to licensed medical practitioners is irrelevant in the present action. In support hereof reference is made to the undisputed facts established by the Answer to Interrogatory No. 5 (App. 38-50) that the purchasers of the device come within the scope of such licensed practitioners and of such exemption.

The revised 1955 Code of Federal Regulations were

adopted pursuant to the provisions of the Act itself quoted above. For the guidance of the Court, Section 502(f) of 52 Stat. 1051, is the same as Section 352(f) of 21 U. S. C., which is also cited in 21 U. S. C. A. 352(f) 1961 Pocket Part at page 316. The pertinent regulation is reported in 21 C. F. R. 1.106 (Title 21 of Food and Drugs Code of Federal Regulations, Revised 1955). Subsection (e) of the said 21 C. F. R. 1.106 (at page 19) provides as follows:

> "(e) Exemptions for drugs and devices shipped directly to licensed practitioners, hospitals, clinics or public health agencies for professional use. Except as provided in Paragraph (g) of this Section, a drug or device shipped directly to or in the possession of a practitioner licensed by law to administer the drug or to use or direct the use of the device, or ship directly to or in the possession of a hospital, clinic or public health agency, for use in the course of the professional practice of such a licensed practitioner, shall be exempt from Section 502(f) (1) of the Act if it meets the conditions of Paragraph (b) (2) and (3), (c) (2), and (3), or (d) (2) and (3) of this Section."

The Ellis Micro-Dynameter is not a prescription drug, nor a veterinary drug, nor a prescription device. Therefore, the references to Paragraphs (b) (2) and (c) (2) and (3), and to (d) (2) and (3) of the said Regulation do not apply.

Moreover, the term "adequate directions for use" is defined by the Secretary himself at the beginning of Section 1.106 of 21 C. F. R. in Paragraph (a) thereof (at page 18) as follows:

> "'Adequate directions for use' means directions under which the layman can use a drug or device safely and for the purposes for which it is intended."

Therefore, the Regulations are consistent in exempting from adequate directions for use those drugs and devices

shipped, not to laymen, but directly to licensed practitioners for professional use.

The matter of shipment to students in the healing arts is also covered in the Regulations in subsection (m) of 21 C. F. R. 1.106 (see page 21 of the Revised 1955 Edition) providing for an exemption for drugs and devices for use in teaching, research and analysis shipped to persons regularly and lawfully engaged in instruction in pharmacy, chemistry or medicine.

The practice of medicine includes the practice generally of the healing art in any of its branches, which includes medical physicians and surgeons, chiropractors, osteopaths and naturopaths, and that the proper, skillful and careful diagnosis of the ailment of a patient is one of the fundamental duties of any of such physicians, 41 Am. Jur. "Physicians and Surgeons," Sec. 92, page 209, who must demonstrate their fitness to government in order to obtain a license to practice in their particular school of the healing arts.

The use of instrumentation in diagnosis by practitioners of the healing arts is in the public interest and the public health is protected by the qualifications of the diagnosing physician to use the instruments as aids in making their own diagnosis. These various practitioners licensed by law to diagnose disease and to treat disease are daily concerned with matters of health and disease in the public interest. For that reason stringent licensure laws, both basic science laws and the special laws of professional licensure, are generally enacted for all practitioners of the healing arts because it is recognized that specialized knowledge and skill is required of them in order to protect the public health, morals, safety and welfare. That is the very reason for the wise policy of the Federal Food, Drug and Cosmetic Act to exempt drugs and devices shipped directly to licensed practitioners for their professional use.

The opinion of the Circuit Court of Appeals for the Seventh Circuit recognizes that: "The conflict in the evidence is primarily between the opinions of Defendants' expert witnesses that the Micro-Dynameter is an effective aid in diagnosis and the Government's expert witnesses that it is not."

Yet said opinion took the position that the fact that the Micro-Dynameter may be used only by licensed practitioners cannot be a basis for an exemption, and said that the Court saw "no reason why a device used solely by licensed practitioners should, for that reason alone, be exempt from that portion of the Act requiring the labeling to bear 'adequate directions for use'."

The basic reason is, which the Court did not consider, that when practitioners schooled in diagnosis use a device harmless in itself for the purpose of diagnosis, the accuracy or inaccuracy of their diagnosis does not depend upon the device, but upon themselves, and upon their own schooling and skill in the art of diagnosis. It is recognized, even by the Court of Appeals for the Seventh Circuit, that the *only* controversy over this device as a useful diagnostic instrument stems from conflicting medical opinions *only*. The medical diagnostician, of necessity, will diagnose according to his own opinion and his own interpretation. The device itself cannot think or speak for the licensed skilled physician. The physician makes the diagnosis, not the device (App. pages 264 to 267; App. page 62).

If the physician is incompetent, it cannot be the fault of an inanimate device, because the fact of his having a license to practice, including the diagnosis of bodily ills, is a license from the State, and if he is incompetent, then the blame lies with a regulatory body of the State of his practice in according him a license to practice upon the public health in the first place. The manufacturer in this case relied

upon the license of the practitioners. The public, in going to the licensed practitioners, relies upon them. The informative opinions contained in bulletins and books which go to the licensed practitioner and not to the public, cannot be misleading or deceptive to the lay public, because they do not receive them; and cannot be misleading or deceptive to the professional users, inasmuch as they are the sovereign judges of the inductive, not deductive, science of medicine, as learned by them in their schools and experience in practice.

Therefore, no requirement of labeling as applied to such written, printed or graphic matter can possibly be necessary for the protection of the public health. The statute 352(f) specifically exempts any device from any such labeling.

Moreover, the Secretary is charged with the mandatory obligation to promulgate regulations exempting such drug or device from such requirement. This applies whether the Secretary has such a regulation or not. And he cannot defeat the exemption by reserving or deleting a regulation thereunder.

In this case, the Secretary did enact such regulations as have been adverted to. The one relied upon primarily, 21 C. F. R. Section 1.106(c) was said to be deleted and "reserved" on December 9, 1960. But it was in force and effect when this case was commenced below and tried. A like regulation is incumbent upon the Secretary. His alleged reservation, which conceivably could have been prompted by this case itself, is one that should and must be restored in the public interest. The opinion of the Court of Appeals for the Seventh Circuit did not construe the proviso exempting clause in Section 352(f), and should have done so. It did not construe the regulation 21 C. F. R. 1.106(c), and should have done so. As a matter

of public policy and in the public interest, Section 352(f) should be construed, and its mandatory requirement upon the Secretary for the enactment of conforming regulations declared.

Instead, the Court of Appeals for the Seventh Circuit in the decision below avoided such construction altogether, although this is a case of first impression under the Federal Food, Drug and Cosmetic Act. This is an important question of federal law which should be settled by this Court.

An inherent contradiction in the opinion appears when it treated of the classification of the MICRO-DYNAMETER as a prescription device, under 21 C. F. R. Section 1.106(d), as contrasted with its proper classification under 21 C. F. R. Section 1.106(e).

First, the opinion took the instrument out of the classification of prescription devices by asserting that the Defendants concede that it is not a prescription device.

Second, the opinion then defines the device, lifting that description from 21 C. F. R. Section 1.106(d), as a prescription device which is potentially of harmful effect or the method of its use with the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of the device. This device cannot be a prescription device under that definition because it is undisputed that the use or misuse of the instrument in diagnosis has no effect whatsoever on the health of the patient (App. p. 272, Par. 436; p. 273, Par. 437).

Third, the opinion then makes the general allegation, notwithstanding this evidence, and without pointing out any finding of the Court to support the statement, that under the Findings of Fact in the instant case the Micro-Dynameter is not safe for use even in the hands of a li-

censed practitioner. But this is in conflict with a finding of the Court of which we complained and still complain that stated: "8. The fact that the Micro-Dynameter may or may not be sold and distributed only to licensed medical practitioners is not relevant in the present action." (App. p. 340, Par. 66.) So the District Court below did not make such finding. Had the District Court, however, said that the device was not safe for use even in the hands of a licensed practitioner, then it is either a prescription device under the classification of 21 C. F. R. Section 1.106(d), and therefore exempt as a matter of law, or else, being a device shipped to licensed practitioners it comes under the general classification of Section 1.106(e) and is therefore exempt as a matter of law.

This device has been in use since 1933 or for a period of nearly thirty years. That very fact alone repels any support for the conclusion that it has the lethal quality attributed to it by this language of the opinion.

Experienced medical physicians testified for the Petitioners below in support of the usefulness of the device (App. pp. 53-68, 184-275). The opinion itself admits that the controversy in the case was a clash of expert opinions. This of itself again repels the notion expressed in the third to the last paragraph of the opinion of the Circuit Court below that this is a "quack" variety instrument.

With deference to the decision of the Court of Appeals below, the Petitioners assert that the statement in the opinion of a general nature that "licensed practitioners are not exempt from the terms of the Act", citing *Drown* v. *U. S.*, 198 F. 2d 999 (CA 9) is altogether inapposite to the issue of exemption of this device. It is quite true that licensed practitioners in general are not exempt from the terms of the Act if they violate the provisions thereof. No licensed practitioner is Defendant or Petitioner herein. There is no claim made in this case that

any licensed practitioner has violated the provisions of the Federal Food and Drug Act by the use of this device. No licensed practitioner who utilized the device testified in this case against the utility of the device in diagnosis. In the *Drown* case cited, a licensed practitioner was a defendant in a criminal case for having violated the terms of the Act in having sold a device, not to another licensed practitioner, but to a layman. Therefore, the exemption contended for herein did not apply in the *Drown* case. The *Drown* case by contrast, clearly points up the distinction between the use of instruments by the lay public and the use of instruments by professional licensed practitioners. The Defendant in the *Drown* case was convicted in a criminal proceeding *of selling* a misbranded device in violation of the Federal Food, Drug and Cosmetic Act. The headnote of the case itself summarizes this essential character of that case as distinguished from the case at bar wherein the sale to a lay person is not here involved. In the *Drown* case there was a finding that a sale was made in California to a lay buyer known by the Defendant to be returning to Illinois to use the device there. Accordingly, when the seller, a chiropractor, raised the question of exemption under the proviso in 21 U. S. C. A. Section 352(f) she had only the argument that the instrument in the hands of the lay person could not harm the lay person. Concerning that the Court said:

> "While the instruments may be harmless in themselves, their danger lies in the possibility that 'ignorant and gullible persons are likely to rely upon them instead of *seeking professional advice* for conditions they are represented to relieve or prevent."

Thus the Court specifically pointed out that the protection of the public health lies in lay people seeking professional advic . That is precisely the contention of the Petitioners in the case at bar. The use therefore of an

instrument harmless in itself sold only to licensed practitioners for their use as professional diagnosticians should bring such a diagnostic instrument within the exemption. On that specific issue this is a case of first impression and of great public importance.

II.

The Court of Appeals for the Seventh Circuit passed the matter of right to jury trial off by citing *United States* v. *Louisiana*, 339 U. S. 699, but this was strictly a conventional and traditional equitable action. Such is not the quality of the action in the case at bar. The Court below said that it is necessary here to note that the Plaintiff seeks only injunctive relief. But the Court failed to note that historically and traditionally that there can be no traditional, conventional and historical equitable action where there is an adequate remedy at law.

The Federal Food, Drug and Cosmetic Act itself contemplates a jury trial. The entire intendment of the Act so indicates. Violations of the Act must be established by the evidence. Upon proof of violations of the Act by such evidence, then either the device may be condemned on Libel for Information or an injunction entered, or both. If an injunction is entered and thereafter violated, even then the accused is entitled to a jury trial in the contempt proceeding. Thus by the very terms of the Act itself, the Plaintiff had an adequate remedy at law wherein the Defendants were entitled to jury trial as a matter of right.

Reference is made, in this connection, to the whole tenor of the Food, Drug and Cosmetic Act in general and Section 334(b) and Sec. 332(b) in particular.

Under the Federal Food and Drug Act and under the Federal Rules of Civil Procedure both, in the action below the trial court should have and could have submitted to the jury the issues of fact, and if the jury found adversely

to the Defendants, then could have entered an injunction upon such findings. There was no equitable or legal reason not to have done so. It is a matter of profound public interest and importance that the right of trial by jury should not be disregarded merely because one of the ancillary remedies of relief, assuming violations to have been first established, is the entry of an injunction. If this procedure adopted in this matter should be permitted to stand, the Federal Food and Drug Administration hereafter may establish guilt against any accused for violations of the Act without jury trial in any case whatsoever. This is contrary to the clear intendment of the Act and the Constitution of the United States.

In *Bruckman* v. *Hollzer*, 152 F. 2d 730 (CA 9) a decision and opinion on this subject was handed down upon analogous facts which is in clear conflict with the decision of the Court below. It was cited and followed in *Leimer* v. *Woods*, 196 F. 2d 828 (CA 8).

III

Reference is made to the Decree of Injunction appealed from (App. pp. 332-342, inclusive). After upholding the Complaint of the Government that the instrument in question was misbranded under 21 U. S. C. 352(a) and 352(f) (1) for being distributed in interstate commerce accompanied by written, printed and graphic matter suggesting the utility of the instrument as an aid to the licensed professional users in diagnosing the state of health or disease of the body, including any of the diseases of man, the trial court then, after entering a prohibitory injunctive order against the dissemination of such material, also entered a general restraining order coupled with a mandatory order enjoining the Defendants from distributing their device in interstate commerce unless it was accompanied by "written, printed, or graphic matter which clearly states every

disease, condition, symptom and purpose for which the article is intended to be used and for which it is represented by any means to the public" (App. p. 341, Par. 68). Thereupon the Court also decreed that it retain jurisdiction for the purpose of enforcing or modifying this decree and for the purpose of granting such additional relief as may hereafter appear necessary or appropriate (App. p. 342, Par. 68).

Thus it becomes impossible for the Petitioners herein to operate without risk of contempt proceedings if they ship the device to their professional users without any material, and also without creating some new and different written, printed or graphic matter, which can have the approval of the Court, and which will not be construable as "substantially to the same effect" as that which was enjoined, being material enjoined because it was said to suggest utility of the device in helping the professional user diagnose every known disease or condition of man.

In a decision of the United States Supreme Court, *Schine Chain Theaters* v. *U. S.*, N. Y. 1948, 68 Sup. Court 947, 334 U. S. 110, Pet. Denied 68 Sup. Ct., 1343, 334 U. S. 831, the Court said (quoting Rule 65(d)):

> "We need not determine whether the provision in question if read, as it must be, in light of the other paragraphs of the decree, would pass muster. For we think the public interest requires that a more specific decree be entered on this phase of the case. The precise practices found to have violated the Act should be specifically enjoined."

In the decision of the Supreme Court of the United States in *Hartford-Empire Co.* v. *U. S.*, 65 Sup. Ct. 373, 324 U. S. 386, and supplemented on other grounds 65 Sup. Ct. 815, 324 U. S. 570, Mandate conformed to 65 F. Supp. 271, the Supreme Court of the United States said:

"The Government also agrees to the elimination of

Paragraph 9 which generally enjoins the Appellants from violations 'as charged in the Complaint'. This concession is required by statute, by the Rules of Civil Procedure, and by our decisions."

The decision of the Court of Appeals below complained of herein conflicts with a prior decision of the Circuit Court of Appeals of the United States for the Seventh Circuit in *Corica* v. *Ragan*, 140 F. 2d 496.

In a case in the Court of Appeals for the Third Circuit, *Bancroft & Sons Co.* v. *Shelley Knitting Mills*, 268 F. 2d 569, the criticized injunction provided, among other things:

> "Defendant * * * be enjoined from (d) Using any labels or hanging any tags bearing Plaintiff's trademark 'Ban-Lon' unless and until approval for the use thereof shall first have been obtained from Plaintiff."

The Court of Appeals for the Fifth Circuit in *Schwegmann Bros. Giant Super Market* v. *Hoffman-LaRoche, Inc.*, 221 Fed. 2d 326, Cert. Den. 76 Sup. Ct. 77, 350 U. S. 839, reference was made to a modification of an injunction, and the Court approved such modification by the trial Court on account of the failure of the original injunction to comply with Rule 65(d).

In *Russell C. House Transfer & Storage Co.* v. *U. S.*, 189 F. 2d 349, a decision of the Court of Appeals for the Sixth Circuit, the Court reversed a judgment for contempt and remanded with instructions to dismiss the contempt charge, because the carrier held in contempt had been enjoined in general terms not to violate the Act and subjected the carrier to contempt proceedings if it should at any time in the future commit some new violations.

In *N. L. R. B.* v. *Kuiner Motors*, 152 F. 2d 816, Modified

on other grounds 154 F. 2nd 1007, the Court of Appeals for the Ninth Circuit struck out a general clause in a cease and desist order.

The Federal Food, Drug and Cosmetic Act itself in 21 U. S. C. A. Section 332(a) describing the availability of injunction as a remedy, refers to jurisdiction "to restrain violations of Section 331 of this Title". This excludes the right to restrain anticipated violations.

The decision of the Court of Appeals for the Seventh Circuit is squarely and directly opposed to the foregoing authorities. The said erroneous decision seeks support in referring to a finding of the trial court that was quoted as a finding that the Defendants unless enjoined will fail to state the purposes and conditions for which it is intended to be used. Then the Court said "when such conduct is anticipated, the fact that the Defendants have not engaged in such conduct in the past does not preclude the issuance of an injunction. *Labor Board v. Express Publishing Co.*, 312 U. S. 426, 435-36." This position of the Circuit Court of Appeals for the Seventh Circuit is directly in conflict with the precedents cited above and with Rule 65(d) of the Federal Rules of Civil Procedure.

Other precedents cited in the opinion refer to past violations and not to prospective anticipatory violations of the Federal Food and Drug Act.

To finally decide this question, becomes a matter of great public importance. If, notwithstanding Rule 65(d), the Federal Food and Drug Administration may enjoin anticipated, prospective, predicted and future violations, and hold an accused to a restraint on the one hand, and a mandatory requirement in conflict with the restraint on the other hand, it will nullify the protection and effectiveness of Rule 65(d) in any proceeding based upon alleged violations of the Federal Food and Drug Act.

CONCLUSION.

For the reasons stated, and under the authorities cited, it is submitted that the decision of the Court of Appeals for the Seventh Circuit was and is in error, and that this Petition for a Writ of Certiorari to that Court to review its action in so holding, as herein sought, is well founded in fact and in law and should be granted.

Respectfully submitted,

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APPENDIX A.

IN THE UNITED STATES COURT OF APPEALS

For the Seventh Circuit.

September Term, 1961—January Session, 1962.

No. 13471

United States of America,
Plaintiff-Appellee,

vs.

Ellis Research Laboratories, Inc., and Robert W. Ellis, an individual,
Defendants-Appellants.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.

March 22, 1962.

Before HASTINGS, *Chief Judge*, CASTLE and SWYGERT, *Circuit Judges*.

HASTINGS, *Chief Judge*. The United States instituted an action against defendants, Ellis Research Laboratories, Inc., and Robert W. Ellis. By its complaint, it sought to enjoin defendants under the Federal Food, Drug, and Cosmetics Act[1] from shipping in interstate commerce a misbranded device intended for use in the diagnosis of disease. After entering findings of fact and conclusions of law, the district court enjoined defendants from intro-

1. § 1 U. S. C. A. §§ 301-392.

ducing the device into interstate commerce when accompanied by the written, printed or graphic matter that was found to be false and misleading. Defendants were further enjoined from introducing the device into interstate commerce "unless such device bears or is accompanied by written, printed, or graphic matter which clearly states every disease, condition, symptom and purpose for which the article is intended to be used * * *."

The device in question is called a Micro-Dynameter, a highly sensitive galvanometer. It consists of a cabinet to which are attached two wires which in turn connect to a variety of electrodes. In operation, the patient may hold an electrode in each hand or he may hold only one electrode while the examiner uses the other electrode as a probe, placing it on various parts of the patient's body. These electrodes are of dissimilar metals, and when they are placed in contact with the body an electric current is generated. The Micro-Dynameter measures the amount of current flow.

The district court found that "the current flowing between the electrodes as used with the Micro-Dynameter is not dependent on the health or diseased condition of the body, but [on] the amount of perspiration on the skin and other similar factors." The court further found that the labeling suggested and represented that the Micro-Dynameter was "adequate and effective for diagnosing practically all disease conditions as well as the health status of man * * *" and that these suggestions and representations were false and misleading. In its final finding of fact, the court found that when sold and distributed, the labeling used in promoting the sale of the Micro-Dynameter "will fail to state the purposes and conditions for which it is intended to be used."

Defendants challenge these findings of the district court.

Under Rule 52(a), Federal Rules of Civil Procedure, 28 U.S.C.A., these findings must stand unless we find them to be clearly erroneous.[2] The conflict in the evidence is primarily between the opinions of defendants' expert witnesses that the Micro-Dynameter is an effective aid in diagnosis and the Government's expert witnesses that it is not. It was the duty of the trier of fact to resolve this conflict.[2] The district court resolved the conflict against defendants. Our examination of the entire record leads us to the conclusion that the district court's findings of fact are not clearly erroneous.

Defendants contend that the Micro-Dynameter is exempt from 21 U.S.C.A. § 352(f)(1) which requires the labeling to bear "adequate directions for use."[3] Unless the Micro-Dynameter falls within the scope of the exemption in the regulations promulgated by the Secretary of Health, Education and Welfare implementing the proviso of section 352(f)(1), it is not exempt from these labeling requirements.

The Micro-Dynameter qualifies as a "device" within the meaning of 21 U.S.C.A. § 321(h) and is thus subject to the provisions of the Act. The fact that the Micro-Dynameter may be used only by licensed practitioners can not be a basis for an exemption. Licensed practitioners are not exempt from the terms of the Act,[4] and we see no reason why a device used solely by licensed practitioners

2. *See National Labor Relations Board v. Aurora City Lines, Inc.*, 7 Cir., ... F. 2d ..... (1962).

3. 21 U. S. C. A. § 352(f) (1) states: "A drug or device shall be deemed to be misbranded—(f) Unless its labeling bears (1) adequate directions for use * * * *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement."

4. *Brown v. United States*, 9 Cir., 198 F. 2d 999 (1952), cert. denied, 344 U. S. 920.

should, for that reason alone, be exempt from that portion of the Act requiring the labeling to bear "adequate directions for use."

The Secretary's regulations provide the conditions under which a drug or device is exempt from the labeling requirements of section 352(f)(1).[5] The only category under which the Micro-Dynameter could possibly be exempt is that of prescription devices,[6] and defendants concede that it is not a prescription device. A prescription device is defined as: "A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of such device * * *."[7] This definition clearly imports that to be a prescription device the device must be safe for use under the supervision of a licensed practitioner. Under the findings of fact in the instant case, the Micro-Dynameter is not safe for use even in the hands of a licensed practitioner. A device whose labeling claims it to be an aid in diagnosing as many diseases as this one, when in fact it is not, is unsafe for use no matter who uses it. We hold that the Micro-Dynameter is not exempt from that portion of the Act requiring the labeling to bear "adequate directions for use."

Defendants urge that the complaint should have been dismissed because of two purported violations of the Act by the Secretary of Health, Education and Welfare. The

5. 21 C. F. R. §§ 1.106-07 (1955 and Supp. 1961).

6. 21 C. F. R. §§ 1.106(d) (1955 and Supp. 1961). In their brief and on oral argument, defendants relied on 21 C. F. R. § 1.106(e) (1955), providing an exemption for qualifying devices shipped directly to licensed practitioners. This section of the Secretary's regulations has now been revoked. 25 Fed. Reg. 12594 (1960). In any event, the revoked section exempted only prescription devices and the Micro-Dynameter does not qualify. See text accompanying note 7 *infra*.

7. 21 C. F. R. § 1.106(d) (1955).

first section the Secretary is accused of having violated is 21 U.S.C.A. § 335 which requires the Secretary to give notice and an opportunity to express his views to a person against whom a *criminal proceeding* is contemplated before reporting the violation to any United States Attorney. Defendants were not warned beforehand that an action was contemplated. Under the terms of this section, however, such warning is required of the Secretary only where criminal proceedings are contemplated. The instant action is a civil action for injunction.

The second section of which the Secretary is accused of having violated is 21 U.S.C.A. § 334(d). This section provides that a condemned device shall "be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct * * *." As the result of a consent decree of condemnation entered in the United States District Court for the Northern District of Indiana in 1956, one of such Micro-Dynameters was turned over to a representative of the Department of Health, Education and Welfare. This Micro-Dynameter was retained by the Department and used in the preparation of the instant action. Defendants contend that the Secretary's failure to sell or destroy this Micro-Dynameter necessitates dismissal of the present action. We do not agree. The Act requires destruction or sale as the court may direct. It does not appear that the court has directed either destruction or sale of the device under the 1956 consent decree. The decree, entered into by Ellis Research Laboratories, Inc., one of the defendants in this action, directed that the Micro-Dynameter be turned over "to a representative of the Department of Health, Education, and Welfare."

We hold that the Secretary of Health, Education and Welfare did not violate the Act by failing to warn defend-

ants before bringing this action or by retaining the Micro-Dynameter pursuant to the 1956 consent decree.

We find no merit in defendants' argument that the injunction sought and granted is an unconstitutional and unwarranted exercise of the regulatory powers exercised by the United States under the Act in question. Defendants contend that the result of the injunction will be to put them out of business. They can have no vested interest in a business activity found to be illegal. It has long been settled that the Act itself is a constitutional exercise of the commerce power. *United States* v. *Walsh*, 331 U.S. 432 (1947).

Defendants' contention that they were entitled to trial by jury is not well taken. Rule 38, F.R.C.P., provides that the right of trial by jury as declared by the Seventh Amendment "shall be preserved to the parties inviolate." The Seventh Amendment declares that "in suits at common law, * * * the right of trial by jury shall be preserved * * *." Plaintiff sought only injunctive relief, and historically such an action has always been equitable in nature with the factual issues raised triable by the court. In *United States* v. *Louisiana*, 339 U.S. 699 (1950); an original action brought to enjoin the State of Louisiana and all persons claiming under it from trespassing on the land underlying the Gulf of Mexico, the Supreme Court stated: "Louisiana's motion for a jury trial is denied. We need not examine it beyond noting that this is an equity action for an injunction and accounting." *Id.* at 706. Accordingly, it is necessary here to note that plaintiff seeks only injunctive relief. The cases cited[8] by defendants where prayers for legal and equitable relief were joined are inapposite. The trial court did not err in deny-

8. *Leimer* v. *Woods*, 8 Cir., 196 F. 2d 828 (1962); *United States* v. *134 Barrels Dried Whole Eggs*, D.C. E.D. Wis., 53 F. Supp. 653 (1943).

ing defendants a trial by jury. The use of an advisory jury under Rule 39(c), F.R.C.P., lies within the discretion of the trial court and is not a matter of right. *Delman* v. *Federal Products Corporation*, 1 Cir., 251 F. 2d 123, 126 (1958).

Defendants attack the injunction on two grounds. First they urge that the scope of the injunction is beyond the bounds of the Act. Next they contend that the injunction is indefinite and uncertain.

Under paragraphs 1(a), (b) and (c) of the injunction, defendants are enjoined from introducing the Micro-Dynameter into interstate commerce accompanied by the labeling found to have been false and misleading. This is in accord with the findings of fact and enjoins a violation of 21 U. S. C. A. § 352(a). The trial court did not err with respect to these three subparagraphs of the injunction.

Paragraph 1(d) of the injunction enjoins defendants from introducing the Micro-Dynameter into interstate commerce unless accompanied by written matter which states every purpose for which it is intended to be used. This portion of the injunction enjoins a violation of 21 U. S. C. A. § 352(f)(1) which requires that the labeling bear "adequate directions for use." This section has been construed to mean that the labeling must include a statement of every purpose for which a drug or device is intended to be used. See *U. E. Irons, Inc.* v. *United States*, 1 Cir., 244 F. 2d 34, 44-45 (1957), cert. denied, 354 U. S. 923; *United States* v. *Hohensee*, 3 Cir., 243 F. 2d 367 (1957), cert. denied, 353 U. S. 976; *Alberty Food Products* v. *United States*, 9 Cir., 194 F. 2d 463 (1952). The court below committed no error in enjoining violations of section 352(f)(1). Had defendants been enjoined merely from violating section 352(a) they could have introduced the Micro-Dynameter into interstate commerce without violating the in-

junction simply by failing to include in the labeling a statement of all purposes for which it was intended to be used. See *United States* v. *Various Quantities of Articles of Drug*, D. C. D. C., 83 F. Supp. 882, 885-86 (1949). The trial court found as a fact that unless enjoined the defendants will "fail to state [in the labeling] the purposes and conditions for which it is intended to be used." When such conduct is anticipated, the fact that defendants have not engaged in such conduct in the past does not preclude the issuance of an injunction. *Labor Board* v. *Express Pub. Co.*, 312 U. S. 426, 435-36 (1941).

With respect to the charge that the injunction is void for indefiniteness, defendants apparently contend that the trial court should have spelled out how the Micro-Dynamometer can be labeled with "adequate directions for use." Such is not the function of the court. If defendants are unable to label their device without running afoul of that portion of the decree enjoining them from utilizing false and misleading labeling, the situation is of their own making. We find no error in the injunction issued by the district court.

In finding the labeling false and misleading, the district court set out a list of some 55 diseases and conditions which defendants claimed their device would be "adequate and effective for diagnosing." These run the gamut of most of the ills affecting "the health status of man." The court further found that the labeling made false and misleading representations that the device "shows what is actually going on down deep in the tissues of the body"; that it "provides the practitioner with the ability to restore at least 80 per cent of previously unhelped cases to health by following its indications"; and, among other equally fantastic claims, that it "constitutes the greatest step forward toward getting sick people well since December 18, 1895."

With apparent good cause the Government argues that defendants' device is of the "quack" variety. There is sound reason in fact and in law for the issuance of the injunction in the form and manner determined by the district court for the protection of the public.

We have considered all other arguments advanced by defendants and find them without merit.

The judgment and decree of the district court appealed from is affirmed.

AFFIRMED.

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In the Supreme Court of the United States

OCTOBER TERM, 1961

No. 929

ELLIS RESEARCH LABORATORIES, INC., a corporation, and ROBERT W. ELLIS, an individual, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the Court of Appeals (Pet. 29-37) is not yet reported. The findings, conclusions and judgment of the United States District Court for the Northern District of Illinois appear at R. 332-342.[1]

[1] "R." references are to the appendix as filed by appellant (petitioner) in the court below; "A.R." references are to appellee's appendix in the Court of Appeals.

JURISDICTION

The judgment of the Court of Appeals was entered on March 22, 1962. The petition for a writ of certiorari was filed on May 2, 1962. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether an instrument or device which is found to be worthless and to have been sold to chiropractors by false labeling claims as to its diagnostic capabilities is exempt from the Federal Food, Drug, and Cosmetic Act under a proviso which authorizes the Secretary to promulgate regulations exempting certain drugs and devices from bearing adequate directions for use.

2. Whether petitioners were entitled as of right to a jury trial in a suit for an injunction to restrain violations of the Federal Food, Drug, and Cosmetic Act.

3. Whether the injunction could properly restrain, in addition to false labeling, shipping the device in commerce unless accompanied by matter stating the use for which the article is intended.

STATUTE AND REGULATIONS INVOLVED

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., provides in pertinent part:

Section 201 (21 U.S.C. 321)

For the purposes of this Act—

* * * * *

(h) The term "device" * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

* * * *

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

Section 301 (21 U.S.C. 331)

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any * * * device * * * that is * * * misbranded.

Section 302 (21 U.S.C. 332)

(a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, * * * to restrain violations of section 301, * * *

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. * * *

Section 502 (21 U.S.C. 352)

A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

* * * *

(f) Unless its labeling bears (1) adequate directions for use; * * *: *Provided*, that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

21 C.F.R. 1.106 and Cum. Supp. (Jan. 1, 1961)
Drugs and Devices; directions for use.

* * * *

(d) *Exemption for prescription devices.* A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(1) The device is:

(i)(a) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(b) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(ii) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(2) The label of the device (other than surgical instruments) bears:

(i) The statement "Caution: Federal law restricts this device to sale by or on the order of a .....," the blank to be filled with the word "physician," "dentist," "veterinarian," or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(ii) The method of its application or use.

(3) The labeling of the device (which may include brochures readily available to licensed practitioners) bears information as to the use of the device by practitioners licensed by law to use it or direct its use: *Provided, however,* That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to use or order the use of such device.[2]

(4) Any labeling, as defined in section 201 (m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate in-

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[2] This paragraph was amended on August 28, 1961, to require full disclosure of all uses and hazards of prescription devices in labeling on or within the dispensing package. 26 F.R. 8389.

formation for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder-piece labeling which calls attention to the name of the device but does not include indications or other use information.

(5) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

STATEMENT

The United States initiated this action under Section 302 of the Food, Drug, and Cosmetic Act to enjoin the interstate distribution of an electrical device, intended for use in the diagnosis of disease in man, alleged to be misbranded because of false and misleading representations in promotional and instructional literature concerning its capability to diagnose a wide variety of diseases and abnormal conditions. (R. 3-14). Petitioners denied the allegations (R. 14-21) and demanded a jury trial. (R. 22-28). On the Government's motion, the jury demand was stricken. (R. 29). The case was tried, and a permanent injunction issued. (R. 332-342). The Court of Appeals for the Seventh Circuit affirmed the decree. (Pet. 37).

A. The device

The Micro-Dynameter is a galvanometer mounted in a metal cabinet. On its face is a scale or meter to measure in milliamperes the flow of current, together with a number of dials which can be set at numbered or lettered positions. The dial settings increase or decrease the resistance to the current flowing through the machine. The current which flows, and is measured by the scale or meter, is generated by closing the circuit between two dissimilar metal "probes". The circuit is closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water. No outside source of electricity is utilized except in the calibration procedure. (R. 69-72, 163-165, 167).

In actual operation, the machine is first supposed to be "calibrated" in an effort to insure consistent results. (R. 166-167). The patient then holds in his hand a combination electrode (or "probe") consisting of a silver pole and a zinc pole. (Ex. 2A, p. 8). A lighted needle then moves across the scale on the face of the device. (R. 168). The reading obtained, according to petitioners, is the "Potential Energy" or "vital reserve" of the body. (Ex. 2A, p. 7). A second reading, obtained by adjusting the knobs on the face of the cabinet, is the "Metabolic Index", and supposedly measures the "exchange rate of cellular waste and nutriment" in the body. (Ex. 2A, p. 7). The final reading, obtained with the same knob settings as the "Metabolic Index", but after the patient takes a deep breath, is the "Oxygenation Index". (Ex. 2A, p. 8).

These readings are recorded on a card (Ex. 2B and Def. Ex. M, R. 324), and by constructing lines between the points indicated two other values are obtained—the "Dynamic Energy" and the "Health Index". These are claimed to show the general state of the health of the body. (Ex. 2A, p. 7, R. 167-169).

With an electrode of antimony alloy placed on the tongue and an iron electrode on the arm, the patient's "Acid Alkaline Balance" is determined. (Ex. 2A, p. 15, R. 169). And in still other tests, one electrode is held in the patient's hand and the other moved over various areas of the body. (Ex. 2A, p. 15, R. 169-171). High readings are claimed to indicate areas of pathology.

B. The evidence as to false labeling

In general, the claims for the machine are that it can discover changes in living tissue by measuring electrical current produced by such tissue changes. (Ex. 2C, p. 4). The government's evidence was designed to show that the current measured is not generated by the human body at all. It arises from the contact of two dissimilar metals on moist substances—skin or a wet towel (R. 96). When the electrodes were immersed in tap water, a reading of 100 on the "Potential Energy" scale was obtained. (R. 170-171).

An electronics engineer analyzed the electrical circuitry of the machine (Ex. 13, R. 70-72) and described its behavior. He explained several factors which influence the readings on this device, such as washing the hands in water, alcohol, or acetone; drying, clapping, or spanking the hands; holding the

hands over the head; or placing the localized electrode near a large vein or an artery. (Ex. 13, pp. 2, 4, R. 72). His test showed that all readings would be affected if a fresh battery were not used in the calibration procedure. (Ex. 13, pp. 2-3).

Two qualified physicians, who had studied the machine, testified that it had no usefulness at all in the diagnosis of disease. (R. 76, 87). Indeed, tests on two cadavers (Ex. 15B, 15C) yielded "Potential Energies" of 90 and 85, "Metabolic Index" of 15 and 10, and in one case (Ex. 15C) an Acid Alkaline Balance of 16. Normal "Potential Energy" is 100, and all readings are supposed to "drop to zero at death". (Ex. 2C, p. 6).

Finally, two physician-witnesses expert in electro-diagnostic equipment, such as the electro-cardiograph and electroencephalograph, testified that the Micro-Dynameter was in no sense comparable, that the readings obtained from it were meaningless, and that such terminology as "Potential Energy" and "Metabolic Index", as used with this machine, had no relation to potential energy or metabolism as those terms are generally understood in the scientific community. (R. 110-121, 144-148).

C. The findings of the trial court and the injunction

The trial court found that the current flowing through the device "is not dependent on the health or diseased condition of the body" but is influenced by "perspiration on the skin and other similar factors" (Finding 4, R. 333); and that the device was not adequate or effective for diagnosing disease. (Find-

ings 7-8, R. 336-338). The court found also that, unless enjoined, the petitioners would continue to distribute the Micro-Dynameter either with labeling that falsely represented its usefulness in diagnosis or with labeling which failed to state the conditions for which it was intended. (Finding 10, R. 339).

The injunction issued by the court (R. 340-342) restrained petitioners from introducing the machine in commerce with the type of labeling described in the findings and prohibited, additionally, the introduction of the device in commerce

> * * * unless such device bears or is accompanied by written, printed, or graphic matter which clearly states every disease, condition, symptom and purpose for which the article is intended to be used and for which it is represented by any means to the public; * * *

ARGUMENT

1. Petitioners argue that, because the device is sold to chiropractors and physicians, it is exempt from the requirements of the Food, Drug and Cosmetic Act, relying specifically upon 21 U.S.C. 352(f)(1) which authorizes the Secretary, by regulation, to exempt devices from the requirement of adequate directions for use. A short answer to this argument is that the statute confers no exemption for false representations to chiropractors or any other medical practitioners, but, on the contrary, provides that all drugs and devices shall be deemed to be misbranded if their labeling is false or misleading in any particular. Diagnostic equipment of this kind must be honestly

represented to prospective purchasers, including licensed practitioners, for whom it is intended.

Section 502(f)(1) (*supra*, p. 3) provides for exemption, established by regulations, only from the requirement that a device bear adequate directions for use. It has no bearing upon a charge brought on the basis of false and misleading labeling under Section 502(a). Even if the device were exempt and the petitioners could have omitted directions for use from the label, the fact is that they did not omit such directions; promotional and instructional literature was sent. It is because these directions and instructional material were shown to be false and misleading, that the device was properly found to be misbranded.

Moreover, even if Section 502(f)(1) were applicable, petitioners have not shown that the Micro-Dynameter meets the conditions upon which the exemption depends. The statute, as noted, does not provide the exemptions, but directs the Secretary to promulgate regulations exempting any drug or device from the "adequate directions" requirement where it "is not necessary for the protection of the public health". The Secretary has promulgated regulations exempting drugs and devices which can be safely used only by professionally trained people from the requirement of adequate directions for use, but this exemption is conditioned upon other labeling directed to the professional users which will enable them safely and effectively to use the drug or device. Petitioner's device, being worthless, is not one that can be used safely and effectively by the medical profession. Nor does it meet the labeling requirements

that are imposed by the exempting regulations. See *supra*, p. 5.

2. There is no substance to the claim that petitioners were entitled as of right to a jury trial in this action for an injunction. The proceeding is a statutory one, unknown to the common law, and is, of course, equitable in nature. Cf. *Porter* v. *Warner Holding Co.*, 328 U.S. 395, 397-398; *Mitchell* v. *Robert De Mario Jewelry, Inc.*, 361 U.S. 288, 292. In contrast to the specific provision for jury trial in the seizure provision of the Act, 21 U.S.C. 334, the statute makes no provision for jury trial in an enforcement proceeding to restrain violations, 21 U.S.C. 332.

3. As set forth in the Statement, *supra*, petitioners are enjoined not only from distributing the device with the type of misbranding shown to have been used, but also restrained from introducing the device in commerce unless accompained by matter stating every disease and purpose for which it is represented to be useful.

It was reasonably anticipated by the trial court (Finding 10, R. 339) that if the petitioners were

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The decision of the court below is not in conflict with *Brückman* v. *Hollzer*, 152 F. 2d 730 (C.A. 9), and *Leimer* v. *Woods*, 196 F. 2d 828 (C.A. 8). Nor is it contrary to the ruling of this Court in *Dairy Queen, Inc.* v. *Wood*, No. 244, this Term, decided April 30, 1962. In each of those cases, the plaintiff had joined prayers for legal and equitable relief in the same action, with issues of fact common to the legal and equitable claims. The rulings protected the right to a jury trial on the issues of fact involved in the suit at law even though the issues were also involved in the equitable action.

enjoined only from using false representations in the promotion of the device, the firm would continue to distribute the Micro-Dynameter without any labeling whatever and without directions as to the function of the article and the manner of its use. This practice would be equally violative of the Federal Food, Drug and Cosmetic Act. Section 502(f) requires a drug or device to be labeled with "adequate directions for use." The courts have consistently held that "adequate directions for use" must include statements of all purposes for which the device is intended by its shipper. *United States* v. *Hohensee*, 243 F. 2d 367 (C.A. 3), certiorari denied, 353 U.S. 976; *Irons* v. *United States*, 244 F. 2d 34, 44 (C.A. 1), certiorari denied, 354 U.S. 923; *Alberty Food Products* v. *United States*, 194 F. 2d 463 (C.A. 9). The scope of the injunction, therefore, is only as broad as necessary to assure compliance with the Act. Certainly, an injunction may reach "like or related" actions which may "fairly be anticipated from the defendant's conduct in the past". *National Labor Relations Board* v. *Express Publishing Company*, 312 U.S. 426, 435-6. A decree is not subject to objection because it was framed "to suppress the unlawful practices and to take such reasonable measures as would preclude their revival," *Ethyl Gasoline Corp.* v. *United States*, 309 U.S. 436, 461.

The claim that the injunction lacks specificity is without merit. The injunction does not enjoin violations "as charged in the Complaint"; nor does it simply enjoin violations of the Act in general terms. The injunction restrains the petitioners from dis-

tributing the Micro-Dynameter or any similar therapeutic device with certain specific false and misleading claims, and it further enjoins the petitioners from interstate distribution of the device in a way which constitutes misbranding because of a failure to bear adequate directions for use. (R. 340-342). Petitioners can be under no illusions as to what is forbidden.

CONCLUSION

The decision below is clearly correct and the petition for a writ of certiorari should be denied.

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